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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,367	04/16/2007	Teruyuki Nagamune	75954-010500	7433
64494 7590 02/12/2009 GREENBERG TRAUIG, LLP (SV) IP DOCKETING 2450 COLORADO AVENUE SUITE 400E SANTA MONICA, CA 90404				
EXAMINER				
SNYDER, STUART				
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1648				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,367

Applicant(s)

NAGAMUNE ET AL.

Examiner

STUART W. SNYDER

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-893)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of the Claims

1. Claims 1-15 are pending. Amendment of claim 11 in Applicants filing of 11/06/2009 is acknowledged.

Election/Restrictions

2. Applicant's election of Group I (claims 1-10) in the reply filed on 11/06/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-10 are examined herein; claims 11-15 are withdrawn from examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, *i.e.*, results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Because the independent claim is indefinite, all dependent claims are likewise indefinite.
4. Claims 6-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an

improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 6 recite "an antibody of a microorganism"; claims 2-5 and 7-10 depend on claims 1 and 6. However, microorganisms do not produce antibodies and thus the phrase does not make sense. Because the independent claim is indefinite, all dependent claims are likewise indefinite.
6. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: There is no connection between the stated purpose of the method "monitor a microorganism" and detection of the antigen/antibody reaction.
7. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 6 recite "monitor a microorganism"; claims 2-5 and 7-11 depend on claims 1 and 6. However, even considering the Specification, the phrase does not make sense; does monitor mean detection of a microorganism, determination of levels of the

microorganism, determination of either the presence of the microorganism as a function of time. Such lack of clarity makes it difficult or nearly impossible to determine if the steps of the method would actually accomplish the stated method. Because the independent claim is indefinite, all dependent claims are likewise indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Stokes, *et al.* The claims are drawn to a method of monitoring (interpreted for examination purposes to mean detecting or determining the level of) a microorganism capable of infecting a laboratory animal, comprising immobilizing an antigen of or antibody to said microorganism on to a microflow channel of a microflow channel chip, flowing a test sample from the laboratory animal through the microflow channel, conducting an antigen/antibody reaction on the chip and detecting the antigen/antibody reaction. Stokes, *et al.* teaches a method to detect *E. coli* on a microfluidic device (biochip), wherein anti-*E. coli* antibodies are immobilized on channel etched in the chip, the chip is exposed to samples that may or may not contain *E. coli* such that antibody/*E. coli* complexes form and

which are subsequently detected using a fluorescently labeled anti-*E. coli* antibody (see Abstract and Experimental sections and figures referenced in the latter, pp 296-298). Thus, each and every limitation of the claim is taught by Stokes, *et al.* which therefore anticipates the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes, *et al.* in view of Morozov and Morozova and Nakayama, *et al.* The additional claim limitations are that said antigen or antibody is deposited onto the chip by electrospray deposition, that the animal is a mouse or rat, and that the pathogen is selected from list of pathogens including *E. coli*.)115a,c:K(B), Sendai virus, *P. aeruginosa* and mouse hepatitis virus.

The teachings of Stokes, *et al.* are described above (see section 8). Stokes, *et al.* does not teach electrospray deposition or use of microfluidic devices for use with samples obtained from mice or rats. Morozov and Morozova teaches that electrospray deposition was a technique available to skilled artisans as a method to deposit biologically active proteins onto biosensors. Nakayama, *et al.* teaches the desirability of determining the infectious state of laboratory mouse and rat

colonies by various pathogens, especially including *E. coli*.)115a,c:K(B), Sendai virus, *P. aeruginosa* and mouse hepatitis virus.

A skilled artisan would find it obvious to combine the methods of Stokes, *et al*, Morozov and Morozova and Nakayama, *et al.* to arrive at the present invention. A skilled artisan would have been motivated to use Stokes, *et al.* as a starting point because of the rapidity and multiplexing ability of the basic method of miniaturized immunoassay; a skilled artisan would have been motivated to use the method of Morozov and Morozova to precisely add biologically active materials to appropriate areas of the biosensor; and a skilled artisan would have been motivated to select for analysis the diseases taught by Nakayama, *et al.* because of their deleterious effect on the animal colonies and the frequency of which the aforementioned pathogens infect such animal colonies.

A skilled artisan would have had a reasonable expectation of success in combining the methods because the method of Morozov and Morozova allows precise yet gentle deposition of proteins onto various substrates used in biosensors and because the method of Nakayama, *et al.* encompasses immunoassays readily adapted to microfluidic applications as taught by Stokes, *et al.*

Thus, the combined teachings of Stokes, *et al.*, Morozov and Morozova, and Nakayama, *et al.* render the instantly claimed invention *prima facie* obvious.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648